# In the United States Court of Federal Claims

# **OFFICE OF SPECIAL MASTERS**

No. 19-1025V

Filed: June 9, 2023

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FF	FREDERICK D. MCBETH,													
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	Petitioner,													*
v.	v.													*
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$\mathbf{A}$	AND HUMAN SERVICES,													
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Scott Taylor, Esq., Urban & Taylor, S.C., Milwaukee, WI, for petitioner. Kyle Pozza, Esq., U.S. Dept. of Justice, Washington, DC, for respondent.

## FACT RULING AND ORDER DENYING MOTION TO DISMISS<sup>1</sup>

## Roth, Special Master:

On July 17, 2019, Frederick D. McBeth ("Mr. McBeth" or "petitioner") filed a petition for compensation in the National Vaccine Injury Compensation Program ("the Program"),<sup>2</sup> alleging that a tetanus toxoid vaccination he received on June 6, 2016 caused him to suffer from Guillain-Barré Syndrome ("GBS"). Petition, ECF No. 1.

In his combined Rule 4(c) Report and Motion to Dismiss, respondent stated that petitioner has not provided adequate proof of vaccination to satisfy the Vaccine Act's requirement, and accordingly, compensation must be denied and the petition dismissed. Respondent's Report, ECF No. 33. Petitioner filed a memorandum in response, maintaining that he has submitted sufficient proof of vaccination and requesting that respondent's motion be denied. Petitioner's Memorandum, ECF No. 45.

<sup>&</sup>lt;sup>1</sup> Because this Ruling contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the Ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the undersigned finds that the identified material fits within this definition, such material will be redacted from public access.

<sup>&</sup>lt;sup>2</sup> The Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 *et seq.* (hereinafter "Vaccine Act" or "the Act"). Hereafter, individual section references will be to 42 U.S.C. § 300aa of the Act.

After carefully analyzing and weighing the evidence presented in this case in accordance with the applicable legal standards, I find that petitioner has submitted sufficient proof of vaccination to satisfy the Vaccine Act's requirement.

# I. Procedural History

The petition was filed on July 17, 2019. Petition, ECF No. 1. Petitioner filed medical records and an affidavit on the same date and a Statement of Completion on September 16, 2019. Petitioner's Exhibits ("Pet. Ex.") 1-7, ECF No. 1; ECF No. 8.

On December 16, 2019, respondent filed a status report requesting that petitioner file his vaccination record, complete medical records for the three years prior to vaccination, and an insurance benefits statement from June 6, 2013 to the present. ECF No. 9.

On March 16, 2020, petitioner filed a status report advising that there were no additional records related to proof of vaccination other than the letter from Dr. Pridipongse Vithespongse already filed, which stated, "This letter is to certify that our records do not indicate that we gave Fred Mcbeth a T. Toxoid on June 6, 2016 or any months prior to June 6, 2016." ECF No. 12; *See* Pet. Ex. 5 at 4. Petitioner further advised that Dr. Vithespongse refused to speak with him or counsel regarding his records, he could not provide any additional information, and suggested a hearing may be appropriate to determine whether petitioner received a tetanus toxoid vaccine on June 6, 2016. ECF No. 12. Petitioner advised that he did not recall receiving medical treatment in the three years prior to June 6, 2016, and all pre-vaccination records had already been filed to the best of his knowledge. Finally, petitioner advised that he was in the process of obtaining his insurance benefits statements and filed a motion for extension of time to do so. ECF No. 14.

An Order was issued on March 17, 2020, granting petitioner's motion for extension of time to file his insurance benefits statements, and directing petitioner to provide some sort of evidence to support his claim that he received a tetanus toxoid vaccine on or about June 6, 2016, such as a receipt of payment, a cancelled check, or a credit card statement. ECF No. 15.

Petitioner filed two additional motions for extension of time on May 1, 2020 and June 17, 2020; both were granted. ECF Nos. 16, 17. On July 31, 2020, petitioner filed his insurance benefits statements. Pet. Ex. 8-9, ECF No. 20. Respondent filed a status report on October 13, 2020 advising that he has not yet been able to review the evidence filed and requested additional time to do so. He also noted that petitioner had not filed any evidence of vaccination other than his word. ECF No. 21.

On October 14, 2020, an Order was issued explaining that the Vaccine Act requires a petitioner to prove receipt of a vaccine by a preponderance of the evidence, and that a special master may not find that a petitioner received a vaccine based on the claims of petitioner alone. ECF No. 22; § 11(c)(1), § 13(a)(1). Thus, petitioner was ordered to present some form of documentary medical evidence to support his claim that he received a tetanus toxoid vaccine on June 16, 2016, or file for dismissal of his claim.

Respondent filed a status report on December 14, 2020, again noting that petitioner had not provided proof of vaccination, advising that he intended to defend the case, and requesting to file his Rule 4(c) Report, which was subsequently ordered. ECF No. 23.

On December 15, 2020, petitioner filed a status report and a Memorandum in Support of Proof of Vaccination. ECF Nos. 25-26. In his status report, petitioner advised that he intended to file a motion for issuance of subpoena to secure specific vaccine records from Dr. Vithespongse. He further noted that it may be necessary to depose the doctor "regarding his recordkeeping and method of tracking vaccine procurement and distribution" once the records were received. ECF No. 25. Petitioner submitted that he had provided sufficient proof of vaccination based on other medical records which reference receipt of a tetanus vaccine. ECF No. 26.

Petitioner filed a motion for issuance of subpoena on December 23, 2020 for all records related to the purchase, acquisition, and administration of any and all tetanus toxoid ("TT"), tetanus and diphtheria ("Td"), or tetanus, diphtheria, and acellular pertussis ("Tdap") vaccines and any medical treatment, related billing statements, or insurance claims forms for Frederick D. McBeth in the possession of Hedrick Medical Clinic and/or Dr. Pridipongse Vithespongse. ECF No. 28.

On January 8, 2021, an Order was issued that addressed petitioner's motion for issuance of subpoena, briefly reviewing petitioner's medical history and noting that the medical records filed in this matter did not support petitioner's claims that he received tetanus vaccines in both April 2016 and/or June 6, 2016, nor did his records associate his development of GBS to the receipt of any tetanus vaccines. ECF No. 30. Further, the undersigned explained that due to the broad scope of information sought by petitioner's subpoena, Dr. Vithespongse should have the opportunity to respond to petitioner's motion for issuance of subpoena. Accordingly, petitioner was ordered to serve a copy of his motion on Dr. Vithespongse, who would then have 30 days to advise whether he objects to or will comply with the subpoena if issued.

After one granted motion for extension of time, on January 11, 2021, respondent filed his objection to petitioner's motion. ECF Nos. 29, 31. Petitioner filed a reply on January 20, 2021, further explaining why his requests were relevant to his case. ECF No. 32.

On February 16, 2021, respondent filed a combined Rule 4(c) Report and Motion to Dismiss, recommending that compensation be denied and the petition dismissed due to inadequate proof of vaccination and because petitioner had not proved causation even if he had been vaccinated as alleged. Respondent's Report ("Resp. Rpt."), ECF No. 33.

Petitioner filed a status report on the same date, advising that while preparing to serve Dr. Vithespongse with the moving papers for issuance of a subpoena, petitioner's counsel learned that Dr. Vithespongse had sold his clinic and retired. The clinic was purchased by Keokuk County Hospital & Clinics ("Keokuk"). Counsel planned to serve both Keokuk and Dr. Vithespongse. ECF No. 34. Petitioner filed proof of service on both parties on February 23, 2021. ECF No. 35. He also filed a status report advising that the CEO of Keokuk clarified that they did not purchase Dr. Vithespongse's clinic but were renting the building and treating his former patients on a limited basis. However, since Keokuk was the current custodian of Dr. Vithespongse's records, they would conduct a search of the records. ECF No. 36.

On March 2, 2021, petitioner filed a letter from Dr. Vithespongse dated February 24, 2021, in which he stated that he had no objection to counsel obtaining petitioner's medical records from Keokuk. ECF No. 37.

An Order was issued on March 3, 2021, granting in part petitioner's motion for issuance of subpoena. Specifically, the Court approved issuance of a subpoena on Keokuk for the purpose of obtaining the following:

(1) records of the administration of tetanus-containing vaccinations administered in April 2016, if the date of the alleged vaccination can be determined, and on June 6, 2016, with any and all personally identifiable information redacted; (2) records of billing for tetanus-containing vaccinations administered in April 2016, if the date of the alleged vaccination can be determined, and on June 6, 2016, with any and all personally identifiable information redacted; (3) records of insurance submissions for tetanus-containing vaccinations administered in April 2016, if the date of the alleged vaccination can be determined, and on June 6, 2016, with any and all personally identifiable information redacted; (4) records reflecting which medical professionals administered tetanus-containing vaccinations in April 2016, if the date of the alleged vaccination can be determined, and on June 6, 2016; and (5) any and all records relating to the treatment of petitioner, Frederick D. McBeth, including but not limited to, medical records, billing statements, and insurance claims form submissions.

ECF No. 38 at 4.

Thereafter, on March 11, 2021 and April 10, 2021, respectively, petitioner filed affidavits of service of the subpoena on Keokuk and the documents he received in response. Pet. Ex. 13-14, ECF Nos. 39-40.

On June 8, 2021, respondent filed a status report noting that the medical records and both handwritten and transcribed letters from Dr. Vithespongse "all indicate that a tetanus vaccine was not administered in April 2016 or June 6, 2016." Respondent requested that petitioner voluntarily dismiss the petition or that the Court order petitioner to respond to the Rule 4(c) Report and Motion to Dismiss and/or show cause as to why the petition should not be dismissed. ECF No. 41.

On July 8, 2021, petitioner filed a status report acknowledging that the lack of documentation of a tetanus shot "may be insufficient to demonstrate to the Special Master that he received the tetanus vaccination as alleged" but requested the opportunity to respond to the Rule 4(c) Report and Motion to Dismiss in full. ECF No. 42.

After one motion for extension of time which was granted, petitioner filed a memorandum in response to respondent's Rule 4(c) Report and Motion to Dismiss on August 19, 2021. ECF Nos. 44-45.

This matter is now ripe for ruling.

## II. Factual Background

# A. Petitioner's Medical History

Petitioner's pre-vaccination medical records are limited, handwritten, and largely illegible. The records from petitioner's primary care physician, Dr. Vithespongse, consist of five pages and include entries from December 31, 2011, one undated from 2013, October 21, 2014, and June 6, 2016, the date of the allegedly causal vaccination.<sup>3</sup> Pet. Ex. 1.<sup>4</sup> The page titled "Statement of Account" does not include any visits between October 21, 2014 and June 6, 2016 but includes "self pay 10/12/2014 and 2016." Pet. Ex. 1 at 5.

The June 6, 2016 record from Dr. Vithespongse documents, "stepped nail Rt foot . . . 10 days ago now painful, swollen . . . bottom Rt middle toe swollen and dark color at puncture". Pet. Ex. 1 at 4. The rest of the record is illegible but does not appear to include any mention of a tetanus toxoid vaccine.<sup>5</sup> The corresponding entry in the "Statement of Account" indicates that petitioner paid \$75.00 at this visit. *Id.* at 5. Dr. Vithespongse provided a letter stating that his records do not indicate that he administered a tetanus toxoid vaccine to petitioner on or prior to June 6, 2016. Pet. Ex. 5 at 4.

On July 23, 2016, petitioner presented to the emergency room ("ER") at the University of Iowa Hospital reporting neck and shoulder pain after suffering four falls over the previous two days. Pet. Ex. 2 at 517. He reported weakness in all extremities but denied dizziness or lightheadedness. *Id.* His vitals were reviewed and significant for blood pressure of 190's/100's. Imaging of the spine was taken and was negative for fracture. Petitioner was admitted to internal medicine for continued evaluation due to ongoing hypertension, weakness, and multiple falls. *Id.* at 522.

Petitioner was seen by an internal medicine physician, Dr. Katherine Harris, on July 24, 2016. Pet. Ex. 2 at 485. Petitioner reported weakness in his right leg beginning four days prior that progressed to both legs and both hands, and numbness in the bottom of his feet for about three to four months: "[p]reviously, it was intermittent but since yesterday it has been constant." *Id.* at 485, 491. He also reported numbness in his hands "which started yesterday and has gotten significantly worse" and felt that he had lost strength in his hands. *Id.* at 485. Petitioner advised that he "went to doctor about a month ago to get a staple removed from his left big toe (had tetanus shot at that time)". *Id.* Dr. Harris noted that petitioner's diabetes mellitus was poorly controlled; she was concerned for GBS, and petitioner was transferred to neurology. *Id.* at 491.

Petitioner was evaluated by a neurologist on the morning of July 24, 2016. Pet. Ex. 2 at 498-504. The record notes an underlying polyneuropathy likely related to diabetes which did not explain his acute symptoms. There was no evidence of stroke or cervical pathology, and AIDP/GBS was suspected. *Id.* at 503. An EMG conducted on July 25, 2016 was consistent with

<sup>&</sup>lt;sup>3</sup> Petitioner's affidavit states that he also received a tetanus toxoid vaccine in "approximately April of 2016". There is no record of an April 2016 visit or tetanus vaccine in Dr. Vithespongse's records. Pet. Ex. 3.

<sup>&</sup>lt;sup>4</sup> Two pages of Dr. Vithespongse's records were also included in Petitioner's Exhibit 5. See Pet. Ex. 5 at 6-7.

<sup>&</sup>lt;sup>5</sup> In his affidavit, petitioner affirmed that Dr. Vithespongse's records fail to note the administration of a tetanus toxoid vaccine on June 6, 2016. Pet. Ex. 3 at 2.

acute demyelinating neuropathy and there was evidence of a superimposed peripheral neuropathy. *Id.* at 873.

Petitioner received five days of IVIG with improvement of symptoms and was discharged to inpatient rehabilitation at Ottumwa Regional Health Center ("Ottumwa") with a diagnosis of GBS, specifically AIDP, on July 29, 2016. Pet. Ex. 2 at 543, 547-48, 551-52, 567. Petitioner was discharged home from rehabilitation on August 19, 2016 and was noted to be doing well with "significant improvement of the gait, endurance, ambulation and mobility." Pet. Ex. 6 at 699. A ramp was placed at his home with a plan for continued physical therapy. *Id*.

On August 24, 2016, petitioner presented to Ottumwa for outpatient physical therapy. Pet. Ex. 6 at 425. On a medical history form, petitioner attributed his development of GBS to an infected toe. *Id.* A plan of care for occupational therapy notes his start of care as August 25, 2016, and that petitioner reported "having difficulties starting in April 2016 that leads (sic) up to [h]ospitalization in July 2016." *Id.* at 430. This record contains no mention of a recent tetanus vaccine. A physical therapy record written by Paul Riggs on August 25, 2016 includes "[p]atient reports that he was in normal health open till [sic] July when he stepped on a staple and got an infection in his foot and had to have a lot of medications and injections after that which might have triggered the Guillain barre problem." *Id.* at 574.

Petitioner subsequently received care for his GBS and associated sequelae at follow-up appointments on September 16, 2016 and December 13, 2016. Pet. Ex. 2 at 630-32, 738-741. He was also hospitalized from October 15 to 16, 2016 for bilateral leg edema that had severely worsened. His recent GBS and treatment was noted. *Id.* at 752-62. He was directed to stop gabapentin, which he had recently started but can cause edema, and was discharged home in stable condition with recommended outpatient physical therapy. *Id.* at 755.

Based on the records, it does not appear that petitioner received any further treatment related to his GBS.

#### **B.** Petitioner's Affidavit

In his affidavit filed on July 17, 2019, petitioner affirmed that he presented to Dr. Vithespongse on June 6, 2016, after he "stepped on a large construction staple puncturing a toe on [his] left foot." Pet. 3 at 1. He stated that Dr. Vithespongse administered a tetanus toxoid intramuscularly into his left deltoid recalling the "exact words Dr. Vithespongse said to [him] prior to the administration of the vaccination." *Id*.

Petitioner affirmed that he reviewed Dr. Vithespongse's records, they are difficult to understand, and that the record from June 6, 2016 does not include that a tetanus toxoid vaccine was administered. Pet. Ex. 3 at 2. Petitioner affirmed that the record documents that he injured his right foot, but it was his left. *Id.* Petitioner further affirmed that he had a tetanus toxoid vaccine administered by Dr. Vithespongse in "approximately April of 2016," but the medical records do not include documentation of this vaccination. *Id.* 

Petitioner described his legs "giving out and began 'quitting', resulting in several falls" which began on or about July 20, 2016, with falling episodes, paralysis, and weakness in his legs that continued to progress on July 21-22, 2016. Pet. Ex. 3 at 2. On July 23, 2016, petitioner "could barely move [his] limbs and could not get out of bed." *Id*. He was driven to the emergency department at University of Iowa Hospital that evening due to increased weakness in both legs, shooting pains from his shoulder into his neck, and constant numbness in his hands. *Id*.

Petitioner affirmed his admission to the University of Iowa Hospital on July 24, 2016, and that his two physicians, Dr. Katherine Harris and Dr. Faisal Fecto, suspected he had GBS after diagnostic testing and physical examination. Pet. Ex. 2 at 2-3. Petitioner affirmed a lumbar puncture on July 25, 2016 confirmed a diagnosis of GBS, and he started IVIG on that date for five days with "slightly improving results." *Id.* at 3.

Petitioner recalled that he was discharged from University of Iowa Hospitals and transported to Ottumwa Regional Health Center on July 29, 2016 for rehabilitation including physical and occupational therapy. Pet. Ex. 3 at 3. He stated that "[a]ccording to Dr. Fecto, I had developed Guillain Barre Syndrome, and the cause of this was the tetanus vaccination that I received on June 6, 2016. Dr. Fecto informed me that there was no other explanation for my Guillain Barre Syndrome." Pet. Ex. 3 at 3.

Petitioner affirmed that he saw neurologist Dr. Laurie Gutmann at University of Iowa Hospitals for a follow-up evaluation on December 13, 2016. Pet. Ex. 3 at 3. Dr. Gutmann noted that petitioner was still experiencing symptoms of weakness and numbness in his legs and hands, and her assessment was Guillain Barre Syndrome. *Id.* Petitioner stated that Dr. Gutmann told him that while he had improved since his July 2016 hospitalization, he "was left with significant sensory deficits", that his diabetic neuropathy had affected his recovery significantly, he "would probably not experience much more recovery", and his condition would "most likely be permanent", making it very difficult to work. *Id.* 

Dr. Gutmann wrote a letter supporting petitioner's medical disability on December 21, 2016, stating that his improvement as it relates to GBS "reached a plateau with continued sensory findings affecting [his] balance and endurance." Pet. Ex. 3 at 3-4. Petitioner affirmed that he continues to suffer the effects of GBS, experiencing electrical shocks, weakness/fatigue in his legs, right leg/knee buckling, and numbness and weakness in both hands, which is "at times debilitating" and "severely limits" his ability to work. *Id.* at 4.

#### C. Insurance Records

Petitioner filed records from Amerigroup Iowa Health and Wellness Plan, a form of Medicaid for the State of Iowa. *See* Pet. Ex. 9. The insurance benefits statement reflects "Beginning Paid Dt: 06/06/2013", but the first date of service reflected is July 29, 2016, when petitioner was hospitalized and after he received the allegedly causal tetanus toxoid vaccine. Pet. Ex. 8 at 1. A medical record from his hospitalization indicates that petitioner was uninsured at the time of his admission. The record from July 24, 2016 states "ED SW was notified by ED PAR that patient was found to have no insurance." Pet. Ex. 2 at 483. In his response to respondent's Motion

to Dismiss, petitioner explained that he applied for Medicaid shortly thereafter and was approved under Presumptive Eligibility with an effective date of coverage of July 25, 2016. Response at 14.

## D. Other Documentation from Dr. Vithespongse's Office

In addition to Dr. Vithespongse's records, petitioner filed a letter from Dr. Vithesponge stating, "This letter is to certify that our records do not indicate that we gave Fred Mcbeth a T. Toxoid on June 6, 2016 or any months previous to June 6, 2016." Pet. Ex. 5 at 4.

In response to petitioner's efforts to secure records providing proof of vaccination a detailed Order issued for service on Keokuk.<sup>6</sup> ECF No. 38. Petitioner filed the records received as result of the subpoena. Pet. Ex. 14. The records included some pages of petitioner's records from Dr. Vithespongse that were already filed<sup>7</sup> and a letter from the CEO of Keokuk, Matthew Ives, confirming "no such billing, insurance, records related to tetanus-containing vaccinations, or purchasing tetanus-containing vaccines exist in our files." *Id.* at 1.

#### **III.** The Parties' Positions

## A. Respondent's Motion to Dismiss

Respondent filed a combined Rule 4(c) Report and Motion to Dismiss on February 16, 2021, asserting that compensation should be denied and the petition dismissed for failure to satisfy the proof of vaccination requirement. Respondent's Report ("Resp. Rpt."), ECF No. 33.

Respondent stated that based on § 11(c)(1) of the Vaccine Act, the Court may not find that petitioner has received a vaccine "based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion." Resp. Rpt. at 2. Respondent argued that the records filed in this matter do not establish that petitioner received a tetanus toxoid vaccination on June 6, 2016 as alleged in the petition or on any other date, and that petitioner did not report a tetanus toxoid vaccine to his providers during his treatment for GBS. *Id.* at 2-3. Further, Dr. Vithespongse submitted a letter specifically stating that his records do not indicate that he administered a tetanus vaccine to petitioner on or prior to June 6, 2016. *Id.* at 7 (citing Pet. Ex. 5 at 4).

Respondent argued that there is insufficient evidence that petitioner was vaccinated in this case, or if he was vaccinated, when the vaccination occurred. Resp. Rpt. at 6. Further, respondent explained that even if petitioner had been vaccinated as alleged, he has not established causation, as he has not submitted any medical evidence or an expert report showing that a tetanus toxoid

<sup>&</sup>lt;sup>6</sup> While preparing to serve a subpoena on Dr. Vithespongse, petitioner learned that Dr. Vithespongse had sold his medical clinic and retired or semi-retired, and that his clinic was purchased by Keokuk County Hospital and Clinics, which was now the custodian of the records of Dr. Vithespongse's patients. ECF No. 34. Accordingly, a subpoena was directed to Keokuk. *See* Pet. Ex. 13. Due to the broad scope of petitioner's subpoena request, Dr. Vithespongse was given the opportunity to respond to petitioner's motion for issuance of subpoena, and he advised in a letter that he had no objections to petitioner's counsel obtaining petitioner's medical records. Pet. Ex. 12.

<sup>&</sup>lt;sup>7</sup> Dr. Vithespongse's records were filed as Pet. Ex. 1, with some pages filed again with his letter as Pet. Ex. 5.

<sup>&</sup>lt;sup>8</sup> Mr. Ives's letter also attested that Keokuk did not purchase Dr. Vithespongse's clinic, nor did it "enter into a formal agreement to be custodian of records . . . but agreed to store patient health records only as a service to patients." Pet. Ex. 14 at 1.

vaccine can cause GBS, that it did so in this case, and that it occurred in a medically appropriate timeframe as required by *Althen. Id.* at 8-10. Respondent concluded that, without documentation that he received a tetanus toxoid vaccine, petitioner has not offered sufficient evidence to establish a Table or off-Table vaccine and his case must be dismissed accordingly. *Id.* at 11.

## **B.** Petitioner's Response

Petitioner filed a response to the Motion to Dismiss on August 19, 2021, arguing that there is adequate evidence in the record that petitioner received a tetanus toxoid vaccination on June 6, 2021, and the Motion to Dismiss should be denied. Petitioner's Response ("Response"), ECF No. 45.

In addition to his affidavit, petitioner argues, there is "at least one" specific reference in the medical records that supports petitioner's receipt of a tetanus toxoid vaccine. When petitioner presented to Dr. Harris on July 23, 2016, he informed Dr. Harris, "while under the stress of an emergent and serious medical condition, that he received a vaccination 'about a month ago", and that his blood pressure was normal at that time. Response at 7; Pet. Ex. 2 at 485. Petitioner contends that "there are several reasonable inferences that can be drawn from Petitioner's contemporaneously recorded statement regarding the receipt of a tetanus vaccination that make his statement both reliable and consistent". *Id.* at 7.

First, he argues that petitioner's recollection of going to Dr. Vithespongse's clinic, having a tetanus vaccination in the context of the staple being removed from his left big toe, and recalling his blood pressure at that visit being normal "supports petitioner's accurate recollection of his visit with Dr. Vithespongse on June 6, 2016." Response at 7-8.

Petitioner acknowledges that the record for that visit is inconsistent with his statements but points out that Dr. Vithespongse's record is incorrect. He had "a staple removed from his left big toe," he did not step on a nail with his right foot or have a painful 3<sup>rd</sup> toe as the record reflects. Response at 8. The inaccuracy of Dr. Vithespongse's record for June 6, 2016 further supports petitioner's credibility as the person who experienced the incident, pain, and infection of his toe as well as his recollection of the location of the injury seven weeks later, particularly in light of a doctor whose records are largely illegible and lack specificity and accuracy. Response at 8.

Petitioner argues that at the time he spoke with Dr. Harris, he had no reason to suspect that his tetanus vaccine was related to the physical symptoms that led to his hospitalization, and he had no motive to be anything but truthful in relaying his medical history to Dr. Harris. *Id.* at 8-9. Petitioner argues he did not learn that the tetanus shot was the likely cause of his GBS until he spoke to Dr. Fecto later during his hospitalization. Response at 9; Pet. Ex. 3. At the time he spoke with Dr. Harris, he was simply relaying his recollection of the most recent treatment he had received, which was on June 6, 2016 from Dr. Vithespongse. Response at 9. Thus, he had no motive to be anything but truthful with Dr. Harris on that date. *Id*.

Second, petitioner argues that his statements to the physical therapist in August 2016 also imply that he received a tetanus vaccination and further corroborates his statement to Dr. Harris.

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<sup>&</sup>lt;sup>9</sup> Petitioner was seen by Dr. Harris in the hospital early in the morning of July 24, 2016. Pet. Ex. 2 at 485.

Response at 9. Petitioner's August 25, 2016 physical therapy record documents that "[p]atient reports that he was in normal health open till [sic] July when he stepped on a staple and got an infection in his foot and had to have a lot of medications and injections after that which might have triggered the Guillain barre problem." *Id.*; Pet. Ex. 6 at 574. Petitioner argues that the "reasonable inference" from this statement is that the "injection" petitioner references is the tetanus vaccine he received on June 6, 2016 after stepping on a staple and developing an infection. Response at 9. Further, petitioner's reference to an "infected toe" as the cause of his GBS, refers to the incident that led him to his June 6, 2016 visit with Dr. Vithespongse where he received the tetanus vaccination. *Id.* Pet. Ex. 6 at 575.

Third, petitioner argues that a reasonable inference from the circumstances surrounding petitioner's June 6, 2016 office visit with Dr. Vithespongse is that a tetanus vaccine was administered. Response at 10. Petitioner argues that there is no dispute that he stepped on a metal object and sustained a puncture wound in his foot, making him a candidate for a tetanus shot. *Id.* CDC guidance and "common sense" dictates that physicians are advised to "... consider penetrating or puncture wounds contaminated, possibly posing a higher risk for tetanus" especially in one who "has not been recently vaccinated for tetanus [and] would be a strong candidate for tetanus shot." Response at 10. Thus, it is reasonable to conclude that based on the medical record on June 6, 2016, petitioner would have received a tetanus vaccination as he alleges. *Id.* 

Fourth, Dr. Vithespongse's "substandard and poorly documented treatment records lead to a reasonable inference that he unintentionally omitted documentation of the tetanus vaccine." Response at 10. Petitioner submits that a review of Dr. Vithepongse's records demonstrates that he is largely disorganized, with records that are partially illegible. Dr. Vithespongse was less than cooperative in producing his records and when counsel inquired about the tetanus vaccination and its lack of documentation in his record, he authored a "very carefully crafted letter in response," stating that the records did not indicate Mr. McBeth was given a T. Toxoid on June 6, 2016 or any months prior to June 6, 2016. Response at 11; Pet. Ex. 5 at 4.

Further, after learning that Keokuk County Hospital and Clinics had "purchased" Dr. Vitespongse's practice, a detailed subpoena for petitioner's records and those related to tetanus vaccine administration and billing from Dr. Vithespongse's clinic<sup>10</sup> was issued. In response, the only record produced was the same one-page record from petitioner's June 6, 2016 office visit that

<sup>&</sup>lt;sup>10</sup> Specifically, and as discussed above, the subpoena covered:

<sup>(1)</sup> records of the administration of tetanus-containing vaccinations administered in April 2016, if the date of the alleged vaccination can be determined, and on June 6, 2016, with any and all personally identifiable information redacted; (2) records of billing for tetanus-containing vaccinations administered in April 2016, if the date of the alleged vaccination can be determined, and on June 6, 2016, with any and all personally identifiable information redacted; (3) records of insurance submissions for tetanus-containing vaccinations administered in April 2016, if the date of the alleged vaccination can be determined, and on June 6, 2016, with any and all personally identifiable information redacted; (4) records reflecting which medical professionals administered tetanus-containing vaccinations in April 2016, if the date of the alleged vaccination can be determined, and on June 6, 2016; and (5) any and all records relating to the treatment of petitioner, Frederick D. McBeth, including but not limited to, medical records, billing statements, and insurance claims forms submissions.

had already been filed. Response at 12. Importantly, there were no records produced for the administration of tetanus vaccinations, billing, or insurance claims for tetanus vaccinations. *Id.* The only inference that can be drawn from the lack of documentation in response to the subpoena is that Dr. Vithespongse "does not maintain records documenting vaccinations administered and if the records once existed, has no system in place for locating and identifying such records." Simply, "Dr. Vithespongse's records have less credibility and cannot be relied upon." *Id.* 

Petitioner submitted that Dr. Vithespongse's practice was not high volume, so the volume of tetanus vaccine records should have been minimal, noting that the 2010 US Census Bureau reported a population of 764 in Hedrick, Iowa, and a total population of 10,511 in the county where Hedrick is located. Response at 12-13 (citations omitted). Since the records of vaccinations given at Dr. Vithespongse's office should have been easy to locate and his clinic was unable to produce any records of tetanus vaccines administered there, it is "highly doubtful that Dr. Vithespongse was operating pursuant to the CDC standard guidelines for documenting patient vaccinations." *Id.* at 13. Petitioner concluded that based on his review of the guidelines, Dr. Vithespongse did in fact fail to operate pursuant to CDC standard guidelines.<sup>11</sup> *Id.* 

Finally, in June 2016, petitioner did not have health insurance. He did not secure health insurance through Medicaid until assisted by the social worker while he was hospitalized in July 2016. Response at 14; Pet. Ex. 8. Thus, the June 6, 2016 tetanus toxoid vaccine would not have appeared on the insurance benefits statement as a covered service. *Id*.

Petitioner concluded that the totality of the record and reasonable inferences that can be drawn from the facts lead to the conclusion that petitioner can demonstrate, by a preponderance of the evidence, that he received a tetanus toxoid vaccination on June 6, 2016. Response at 15. Therefore, as a matter of law, the petition should not be dismissed. *Id*.

#### IV. Legal Standard

Under the Vaccine Act, providing proof of vaccination is a threshold matter in order to prevail under either a "Table" injury in which causation is presumed, or an "off-Table" injury, in which petitioner identifies a causal link between the vaccine and the alleged injury. § 300aa–11(c)(1)(A) and (B). Petitioner must first prove by a preponderance of the evidence that he "received a vaccine set forth in the Vaccine Injury Table." § 300aa-11(c)(1)(A). A special master shall assess "the record as a whole" and may not "find that a petitioner received a vaccine 'based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion." *Rich v. Sec'y of Health & Human Servs.*, No. 12–742V, 2013 WL 4476751 (Fed. Cl. Spec. Mstr. July 26, 2013) (§ 300aa–13(a)(1)).

Although contemporaneous documentation of vaccination from a healthcare provider is the best evidence that a vaccination occurred, it is not absolutely required in all cases. *Centmehaiey v. Sec'y of Health & Human Servs.*, 32 Fed. Cl. 612, 621 (1995) ("[t]he lack of contemporaneous documentary proof of a vaccination ... does not necessarily bar recovery"). Indeed, as Vaccine Rule 2 states, "[i]f the required medical records are not submitted, the petitioner must include an

<sup>&</sup>lt;sup>11</sup> *See* U.S. Dep't. of Health & Human Servs., *Vaccine Documentation*, https://www.cdc.gov/vaccines/hcp/adults/downloads/standards-documentation.pdf.

affidavit detailing the efforts made to obtain such records and the reasons for their unavailability." Vaccine Rule 2(c)(2)(B)(i). Furthermore, if a petitioner's claim is "based in any part on the observations or testimony of any person, the petitioner should include the substance of each person's proposed testimony in a detailed affidavit(s) supporting all elements of the allegations made in the petition." Vaccine Rule 2(c)(2)(B)(ii).

Special masters have thus found that vaccine administration occurred even in the absence of direct documentation. In such cases, preponderant evidence was provided in the form of other medical records and/or witness testimony. For example, corroborative, though backward-looking, medical notations have been found to tip the evidentiary scale in favor of vaccine receipt. Lamberti v. Sec'y of Health & Human Servs., No. 99-507V, 2007 WL 1772058, at \*7 (Fed. Cl. Spec. Mstr. May 31, 2007) (finding multiple medical record references to vaccine receipt constituted adequate evidence of administration); Groht v. Sec'y of Health & Human Servs., No. 00-287V, 2006 WL 3342222, at \*2 (Fed. Cl. Spec. Mstr. Oct. 30, 2006) (finding a treating physician's note— "4/30/97—Hep B. inj. # 1 (not given here) (pt. wanted this to be charted)"—to be sufficient proof of vaccination); Figueroa v. Sec'y of Health & Human Servs., No. 10-705V, 2014 WL 6819494, at \*4 (Fed. Cl. Spec. Mstr. Nov. 7, 2014) (finding sufficient proof of vaccination where subsequent medical records documented that petitioner consistently reported receiving the subject flu vaccination); Beckner v. Sec'y of Health & Human Servs., No. 11-668V, 2013 WL 3353993, at \*8 (Fed. Cl. Spec. Mstr. Apr. 25, 2013) (finding sufficient proof of vaccination where a medical record created approximately a month after petitioner's alleged receipt of the subject vaccine documented petitioner's report of his vaccination and the statement was made "for the purpose of facilitating diagnosis and treatment of his condition...[and] the vaccination was received in such close temporal proximity to petitioner's admission that misremembering is unlikely"). But see Matthews v. Sec'y of Health & Hum. Servs., No. 19-414V, 2021 WL 4190265 (Fed. Cl. Spec. Mstr. Aug. 19, 2021), aff'd, 157 Fed. Cl. 777 (2021) (finding insufficient proof of vaccination where petitioner's numerous contemporaneous medical records, petition, and subsequent filings were inconsistent in reporting whether he received a flu vaccine that season and identifying the time at which he allegedly received the vaccine).

In addition to corroborative medical records, witness testimony can also help establish a sufficient basis for a finding that a vaccine was administered as alleged. *Alger v. Sec'y of Health & Human Servs.*, No. 89–31V, 1990 WL 293408, at \*2, 7 (Fed. Cl. Spec. Mstr. Mar. 14, 1990) (oral testimony from a parent and the doctor who administered the vaccine was "more than adequate to support a finding that the vaccine was administered"). The Court of Federal Claims has recognized the existence of precedent supporting the proposition that a court may base a finding of vaccination on lay testimony. *Epstein v. Sec'y of Health & Human Servs.*, 35 Fed. Cl. 467, 478 (Fed. Cl. 1996); *see also Brown v. Sec'y of Health & Human Servs.*, 18 Cl. Ct. 834, 839–40 (1989) (proof of vaccination in the absence of contemporaneous medical records established via testimony of petitioner's parent, her personal calendar, and evidence of a charge for the vaccine on the physician's billing statement), *rev'd on other grounds*, 920 F.2d 918 (Fed.Cir.1990); *Gambo v. Sec'y of Health & Human Servs.*, No. 13-691V, 2014 WL 7739572, at \*3 (Fed. Cl. Dec. 18, 2014).

#### V. Discussion

The only issue to be decided here is whether petitioner has provided sufficient proof of vaccination.

Petitioner alleges that he received a tetanus vaccine on June 6, 2016, but the contemporaneous medical records do not contain a record of a vaccine given on that date. His doctor, Dr. Vithespongse, submitted a letter that his records do not indicate that a tetanus vaccine was given to petitioner on June 6, 2016 or otherwise. Pet. Ex. 5 at 4. Petitioner and his counsel have pursued many avenues in an effort to obtain proof that he received a tetanus vaccine on June 6, 2016, including contacting Dr. Vithespongse on multiple occasions and issuing subpoenas for records that Dr. Vithespongse either never maintained or was no longer in custody of after he retired from practice. Although petitioner has been unable to produce contemporaneous record proof of his alleged vaccination, the record as a whole nonetheless provides preponderant evidence that petitioner more likely than not received a tetanus toxoid vaccine on June 6, 2016.

Dr. Vithespongse's June 6, 2016 office record lacks any reference to the administration of a tetanus vaccine but also incorrectly documents the reason for petitioner's visit. Dr. Vithespongse documented that petitioner stepped on a nail with his right foot injuring his 3<sup>rd</sup> toe, when petitioner affirmed that he stepped on a construction staple puncturing the big toe on his left foot. Pet. Ex. 1 at 4; Pet. Ex. 3 at 1. Dr. Vithespongse also documented petitioner's blood pressure on that date as 120/8; presumably meant to be 120/80. Pet. Ex. 1 at 4. In addition to the incorrect information documented, Dr. Vithespongse's records are mostly illegible and unreliable. *See* Pet. Ex. 1.

The first mention in the medical records of petitioner's receipt of the subject tetanus vaccine was on July 24, 2016, upon admission to University of Iowa Hospitals. *See* Pet. Ex. 2 at 485. When Dr. Harris examined petitioner on that date, petitioner provided his recent medical history which included that he "went to the doctor about a month ago to get a staple removed from his left big toe (had tetanus shot at that time), was told BP was normal." *Id.* Petitioner's August 25, 2016 physical therapy record documents, "[p]atient reports that he was in normal health open till [sic] July when he stepped on a staple and got an infection in his foot and had to have a lot of medications and injections after that which might have triggered the Guillain barre problem." Pet. Ex. 6 at 574. Petitioner consistently reported that he stepped on a construction staple, had an infection, and received a vaccine. Pet. Ex. 2 at 485; Pet. Ex. 6 at 574-75; Pet. Ex. 3.

Petitioner's initial report of receipt of a tetanus vaccine came at a time when accuracy was of the utmost importance, when his medical history was crucial for determining the diagnosis and treatment of his progressing condition that involved multiple falls, leg weakness, and an inability to walk. See Cucuras v. Sec'y of Health & Human Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993) ("Medical records, in general, warrant consideration as trustworthy evidence . . . With proper treatment hanging in the balance, accuracy has an extra premium."); but see Kirby v. Sec'y of Health & Human Servs., 993 F.3d 1378, 1382-83 (Fed. Cir. 2021) (clarifying that Cucuras does not stand for the proposition that medical records are presumptively accurate and complete). There was no litigation pending and petitioner was unaware that a tetanus vaccine could be responsible for his condition. He knew only that when questioned about his recent medical history, he had stepped on a metal construction staple, developed an infection, went to his physician, and received medication and a vaccine. This is what he reported to treating physicians and what is contained in his affidavit.

The factual inaccuracies of the June 6, 2016 medical record aside, there is no dispute that petitioner stepped on a metal object, sustained a wound and infection in his foot, and presented to

Dr. Vithespongse on June 6, 2016 for that injury. Petitioner argues that "common sense" would dictate that a patient presenting to his physician with a puncture wound and infection from a metal object would be a candidate for a tetanus shot, and it is therefore reasonable to conclude that he received a tetanus shot on that date. Response at 10.

Petitioner went to great lengths trying to communicate with Dr. Vithespongse. His counsel spoke to the CEO of the medical facility that became the custodian of Dr. Vithespongse's records and issued a broad subpoena seeking all records from Dr. Vithespongse's clinic related to the general administration of, billing for, and insurance claims submissions for tetanus vaccinations given at the clinic. These steps were taken in an effort to locate some record of petitioner's receipt of a tetanus vaccine and/or to demonstrate that the record-keeping system in place at Dr. Vithespongse's clinic was grossly lacking. See Mot. to Issue Subpoena, ECF No. 28. The broad scope of the subpoena issued for Dr. Vithespongse's office-wide records failed to produce any responsive records for any vaccinations given at that medical office and resulted only in petitioner's sparse record that had been previously filed. See Pet. Ex. 14. The lack of any existing responsive documentary proof of tetanus vaccines administered by Dr. Vithespongse's office aside, petitioner and his counsel's efforts to secure proof of vaccination in this case were frustrated by a medical office that was disorganized and lacked proper documentation and a doctor who was unhelpful to his patient, providing a letter stating that his "records do not indicate that we gave Fred McBeth a T. Toxoid on June 6, 2016 or any months previous to June 6, 2016." Pet. Ex. 5 at 4. However, other than petitioner's sparse and largely illegible record containing incorrect facts about the reason for his June 6, 2016 visit, it is unclear what other records Dr. Vithespongse relied on in writing his letter.

Proof of vaccination is a requirement for Program cases, but a "lack of contemporaneous, documentary proof of a vaccination does not necessarily bar recovery." *Centmehaiey*, 32 Fed. Cl. at 621. There must, however, be some medical documentation or other corroboration to support petitioner's claim. It is not the fault of petitioner that he sought care from a physician who had poor recordkeeping practices and was winding down his practice. Here, on July 24, 2016, the day after petitioner presented to the emergency room following multiple falls due to lower extremity weakness and an inability to walk, he reported to Dr. Harris that he received a tetanus vaccine on June 6, 2016 after stepping on a construction staple. The existing case law supports that notations in medical records, even when reported by the petitioner or another individual with knowledge, can corroborate proof of vaccination. *See Hinton v. Sec'y of Health & Hum. Servs.*, No. 16-1140, 2023 WL 3815047 (Fed. Cl. May 15, 2023). Further, a single notation of a statement made in the process of seeking medical care can satisfy the proof of vaccination requirement. *See Groht*, No. 00-287V, 2006 WL 3342222 at \*2. Thus, the hospital record from July 24, 2016, taken with petitioner's affidavit, provides sufficient corroboration to support his allegation that he received a tetanus vaccine on June 6, 2016.

#### VI. Conclusion

Based on my review of the record as a whole, I find that petitioner has established by preponderant evidence that he received a tetanus toxoid vaccine on June 6, 2016. Respondent's Motion to Dismiss is **DENIED.** 

Within thirty (30) days, the parties shall file a joint status report advising the Court of how they would like to proceed.

Accordingly, the following is hereby ORDERED:

By no later than Monday, July 10, 2023, the parties shall file a joint status report advising the Court of how they would like to proceed.

IT IS SO ORDERED.

s/ Mindy Michaels RothMindy Michaels RothSpecial Master